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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26-I-2007
C(2007)315

NOT FOR PUBLICATION

COMMISSION DECISION

of 26-I-2007

**amending the marketing authorisation for "TARGRETIN - bexarotene", a
medicinal product for human use, granted by Decision C(2001)818**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION DECISION

of 26-I-2007

amending the marketing authorisation for "TARGRETIN - bexarotene", a medicinal product for human use, granted by Decision C(2001)818

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹,

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93², and in particular the third subparagraph of Article 4 (5) and the first subparagraph of Article 5 (7) thereof,

Having regard to the notifications submitted by Ligand Pharmaceuticals UK Ltd under Article 4(1) and Article 5(1) of Regulation (EC) No 1085/2003,

Whereas:

- (1) Between 4 July 2006 and 4 January 2007, the European Medicines Agency acknowledged the validity of the type IA notification(s) and accepted the type IB variation(s) submitted. It informed the marketing authorisation holder accordingly and prepared a list of the notification(s). The variation(s) took effect from the date of the communication of the acknowledgement of validity or acceptance by the European Medicines Agency / within 30 days of the date of acknowledgement, by the European Medicines Agency, of receipt of the valid notification(s).
- (2) The marketing authorisation should be updated, and Decision C(2001)818 of 29 March 2001 amended accordingly.
- (3) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2001)818 should therefore be replaced,

¹ OJ L 136, 30.4.2004, p. 1

² OJ L 159, 27.6.2003, p. 24.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2001)818 is amended as follows:

1) The following list of notifications for minor variations is added to the updated marketing authorisation.

Application number	Scope (EU numbers affected)
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EMEA/H/C/326/IA/021	5 (IA) (EU/1/01/178/001)
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EMEA/H/C/326/IB/016	42.a.1 (IB) (EU/1/01/178/001)
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2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex II is replaced by the text set out in Annex II to this Decision;

4) Annex III B is replaced by the text set out in Annex III B to this Decision.

Article 2

This Decision is addressed to Ligand Pharmaceuticals UK Ltd, Innovis House, 108 High Street, Crawley, West Sussex RH10 1BB, UNITED KINGDOM.

Done at Brussels, 26-I-2007

For the Commission

Heinz ZOUREK

Director-General